► AO 120 (Rev. 2/99)

TO:

Mail Stop 8 Director of the U.S. Patent & Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450

REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK

		15 U.S.C. § 1116 you are hereby advised that a court action		
		<u>District California</u> on the ✓ Patents	or Trademarks:	
DOCKET NO. CV 11-02405 JCS	DATE FILED 5/17/2011	U.S. DISTRICT COURT 450 Golden Gate Avenue, 16 th Floor, S	an Francisco CA 94102	
PLAINTIFF	<u> </u>	DEFENDANT	all Flancisco CA 94102	
IRIDEX CORP		ALCON, INC., ET AL.		
		'		
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER DE PATENT OR TR	HOLDER OF PATENT OR TRADEMARK	
16,800,076		***See Attach Compl	***See Attach Complaint***	
² 7, 537, 593	<u> </u>			
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To Ale t.	ove entitled case the	e following patent(s) have been included:		
		tonowing patent(s) have been included.		
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infringe the '593 patent by its manufacture, use, sale, offer for sale and/or importation of products within this judicial district and elsewhere in the United States that infringe one or more claims of the '593 patent. Examples of infringing products include 20-gauge, 23-gauge and 25-gauge soft tip cannulas with colored silicone ends sold under one or more the product names Accurus[®] Surgical System 23-Gauge Soft-Tip Cannula, Grieshaber® DSP and/or Micro-Incision Vitrectomy Surgery ("MIVS") tips, product numbers including but not limited to 8065149525, 8065149523 and 8065149520, sold alone or as part of a Grieshaber® backflush device or as part of a package of instruments sold to work with the Constellation® Vision System. The Alcon colored soft tip cannulas are especially made or adapted for use in the methods claimed in the '593 patent and are not staple articles suitable for substantial noninfringing use. Aware of this and with knowledge of the '593 patent, Alcon instructs and Alcon encourages the use of Alcon colored soft tip cannulas in ophthalmic surgical procedures, including vitrectomy surgery, as "active and passive aspirators" and highlights the "green tip color" as improving visualization. On information and belief, Alcon sells the Alcon colored soft tip cannulas individually or as part of a system to doctors who purchase these Alcon products and use them in ophthalmic surgeries, including vitrectomy surgeries, upon Alcon's instruction and encouragement. On information and belief, when Alcon so instructs and encourages, it intends that the doctors will use the Alcon colored soft tip cannulas, the Grieshaber® backflush device and the Constellation® Vision System in ways that infringe the '593 patent and the doctors in fact do use these Alcon products in ways that infringe the '593 patent. Alcon's actions infringe one or more of the '593 patent claims, including but not limited to claims 13 and 21.

29. On information and belief, Alcon was aware of the '593 patent prior to the filing of this Complaint but recklessly continued to make, use, sell, offer for sale and/or import products, and instruct and encourage doctors to use these products in ophthalmic surgeries, knowing that such actions constitute a high likelihood of infringement of the '593 patent. Alcon acted and continues to act despite an objectively high likelihood that its actions constituted and continue to constitute infringement of a valid and enforceable patent; this objectively-defined risk was so obvious that it should have been known to Alcon; and in fact Alcon acted and continued to act



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knowing of this objectively-defined risk. Alcon's infringement of the '593 patent is thus willful.

- 30. Alcon's infringement of the '593 patent has caused and, unless enjoined, will continue to cause, irreparable harm to Iridex. Iridex has no adequate remedy at law and is entitled to a permanent injunction against further infringement.
- 31. Iridex has suffered and will continue to suffer damage to its business by reason of Alcon's acts of infringement of the '593 patent as alleged herein and Iridex is entitled to recover from Alcon the damages sustained as a result of Alcon's acts pursuant to 35 U.S.C. § 284.
- 32. Iridex is informed and believes, and on that basis alleges, that Alcon's actions make this an exceptional case within the meaning of 35 U.S.C. § 285, which entitles Iridex to an award of attorneys' fees.

THIRD CLAIM FOR RELIEF

(Declaratory Judgment That Iridex Is The Sole Owner of the '076 and '593 Patents)

- 33. Iridex incorporates by reference paragraphs 1 through 20 above.
- 34. To the extent Alcon contests Iridex's ownership of the '076 and '593 patents, by asserting that Mr. Hallen is a co-inventor of either or both of the '076 and '593 patents, Iridex requests a declaration of its rights as the sole owner of the '076 and '593 patents.
- 35. Mr. Hallen was hired by RetinaLabs as Vice President, Research and Development of RetinaLabs, to use his inventive faculties to contribute to the development of RetinaLabs technology. For example, Mr. Hallen was hired for the purpose of further developing ophthalmic devices. As a result of Mr. Hallen's employment, position and responsibilities, he had an obligation to assign all rights in any invention developed in the course of his employment to RetinaLabs. Indeed, Mr. Hallen demonstrated that he understood this obligation by assigning to RetinaLabs all rights in the inventions he participated in developing during his employment, many of which resulted in patents in which Mr. Hallen assigned all of his rights to RetinaLabs. Had Mr. Hallen's contributions to the inventions of either the '076 and /or '593 patents risen to the level of inventorship, his rights would have been similarly assigned to RetinaLabs and would now be owned by Iridex.
 - 36. To the extent Alcon contests Iridex's ownership of the '076 and '593 patents,



Alcon has created a case or controversy regarding ownership of the '076 and '593 patents and Iridex requests a declaration of Iridex's rights as the sole owner of the '076 and '593 patents to resolve this dispute.

PRAYER FOR RELIEF

WHEREFORE, Iridex Corp. prays for the following relief:

- 1. That judgment be entered in favor of Iridex Corp. with a finding that Alcon, Inc., Alcon Laboratories, Inc., and Alcon Research Ltd., have infringed and are infringing claims of United States Patent Nos. 6,800,076 and 7,537,593 in violation of 35 U.S.C. §271;
- 2. That judgment be entered in favor of Iridex Corp. with a finding that Iridex Corp. is the sole and exclusive owner of United States Patent Nos. 6,800,076 and 7,537,593;
- 3. That Iridex Corp. be granted an accounting of all damages sustained as a result of the infringement of Alcon, Inc., Alcon Laboratories, Inc., and Alcon Research Ltd., of United States Patent Nos. 6,800,076 and 7,537,593 as herein alleged;
- 4. That Iridex Corp. be awarded actual damages with prejudgment interest according to proof and enhanced damages pursuant to 35 U.S.C. §284;
- 5. That a permanent injunction be issued pursuant to 35 U.S.C. §283 enjoining Alcon, Inc., Alcon Laboratories, Inc., and Alcon Research Ltd., their officers, agents, servants, employees, and all other persons acting in concert or participation with them from further infringement of United States Patent Nos. 6,800,076 and 7,537,593;
- 6. That this case be decreed an "exceptional case" within the meaning of 35 U.S.C. §285, and that reasonable attorneys' fees, expenses, and costs be awarded to Iridex Corp.; and
 - 7. That Iridex be awarded such further relief as the Court deems just and proper.



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Iridex Corp. hereby demands a jury trial as to all issues triable to a jury.

DATED: May 17, 2011

Respectfully submitted,

KILPATRICK TOWNSEND & STOCKTON LLP

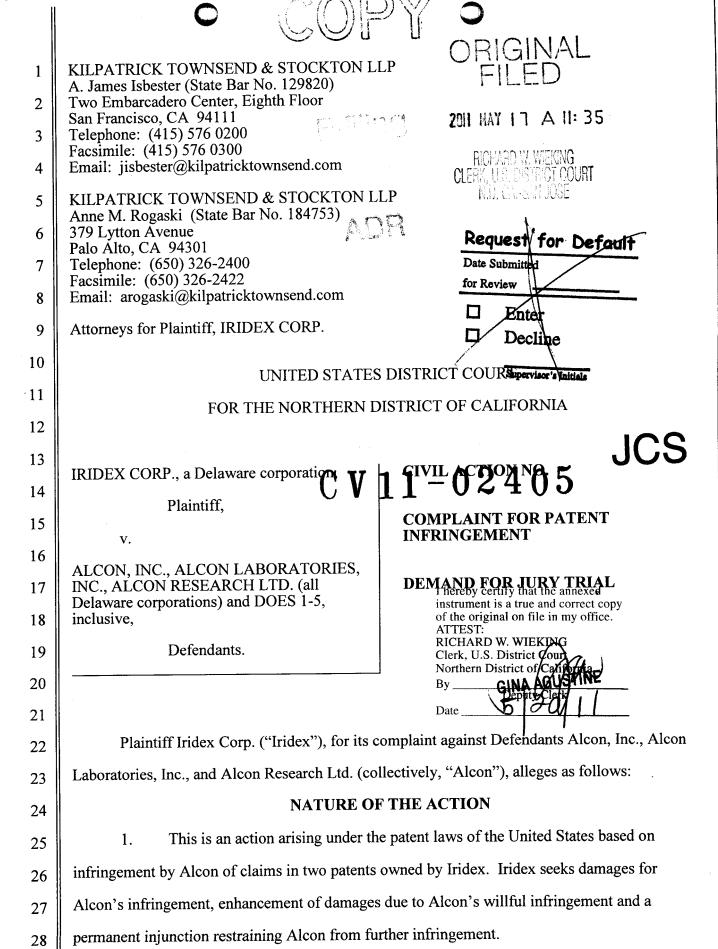
By:

A. JAMES ISBESTER ANNE M. ROGASKI

Attorneys for Plaintiff, IRIDEX CORP.

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PARTIES

- 2. Iridex is a corporation organized and existing under the laws of Delaware with its principal place of business located at 1212 Terra Bella, Mountain View, CA 94043. Founded in 1989, Iridex is a worldwide leader in developing, manufacturing and marketing innovative and versatile light-based medical systems and delivery devices.
- 3. On information and belief, Defendant Alcon, Inc., is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 6201 S. Freeway, Fort Worth, Texas 76134. On further information and belief, Alcon, Inc. is the parent corporation of Alcon Laboratories (the selling, marketing and distribution arm of Alcon, Inc.) and Alcon Research, Ltd. (the United States manufacturing, research and development arm of Alcon, Inc.).
- 4. On information and belief, Defendant Alcon Laboratories, Inc., is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 6201 S. Freeway, Fort Worth, Texas 76134.
- 5. On information and belief, Defendant Alcon Research Ltd., is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 9965 Buffalo Speedway, Houston, Texas 77054 and a manufacturing facility at 15800 Alton Parkway, Irvine, California 92618.
- 6. Iridex is ignorant of the true names and capacities of Defendants sued herein as Does 1 through 5, inclusive, and therefore sues said Defendants by such fictitious names. Iridex will amend this Complaint, if necessary, to allege their true names and capacities when ascertained.

JURISDICTION

7. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§1331 and 1338(a). This Court has personal jurisdiction over the Alcon defendants because, on information and belief, each has purposely availed itself of the privilege of conducting activities within this State and District, at a minimum, through sales of the accused products and



other products for use in ophthalmic procedures in this State and District and by marketing the accused products and other products (including providing samples) at trade shows and/or scientific exhibitions such as the annual meetings of the Retina Society and the American Academy of Ophthalmology in this State and District.

VENUE

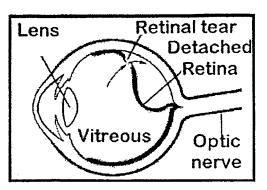
8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§1391 and 1400(b) as the Alcon defendants have done business in this judicial district and have committed and continue to commit acts of patent infringement in this judicial district.

INTRADISTRICT ASSIGNMENT

9. Because this is an Intellectual Property Case, it may be assigned on a district-wide basis pursuant to Civil Local Rule 3-2(c).

BACKGROUND

10. Retinal detachment is a serious eye condition requiring early treatment to avoid impairment or loss of vision. It can occur due to injury to the eye or as a result of cataract surgery. The retina is a fine layer of nerve cells that covers the inside back portion of the eye. If it thins, tears or holes in the retina can occur, which may lead to retinal detachment (see figure, below).



Various procedures have been developed to treat retinal detachment, including laser photocoagulation to seal the tears as well as more complicated surgical procedures in which the detached portion of the retina is pressed against the back wall of the eye. In connection with the latter procedure, the tip of a cannula (tube) can be used to press the detached portion of the retina against the back wall of the eye and the cannula can also be used to remove fluids or introduce air or gas to the eye. The tip of the cannula must be soft to avoid damaging the eye. A disadvantage



of cannulas in the past was the tip of the cannulas was transparent, making it difficult to visualize the tip in the eye during surgery, critical for most effective use.

- More serious ophthalmic surgical procedures include vitreoretinal procedures, in which the vitreous body is cut away from the retina and removed from the eye. The vitreous cavity may then be filled with air or gas to push the retina back against the wall of the eye, after which fluid fills the vitreous cavity. During vitreoretinal procedures, a cannula can be used to push the detached portion of the retina against the back wall of the eye as well as to fill the vitreous cavity with air or gas and remove fluids from the eye.
- 12. The patents asserted in this case, United States Patent Nos. 6,800,076 and 7,537,593, are directed to cannulas with soft tips (and their use in ophthalmic surgery) that are at least partially colored to allow for better visibility in the eye, resulting in safer and easier manipulation around the delicate eye tissue during ophthalmic surgery.
- 13. Iridex manufactures and sells GreenTip™ Soft Tip Cannulas, covered by and marked with United States Patent Nos. 6,800,076 and 7,537,593, to doctors for use in ophthalmic surgery. RetinaLabs began selling its GreenTip™ Soft Tip Cannulas in or about January 2007. In or about January 2010, Iridex began distributing RetinaLabs' GreenTip™ Soft Tip Cannulas. RetinaLabs was acquired by Iridex in or about April of 2010, at which time Iridex began selling the GreenTip™ Soft Tip Cannulas as an Iridex product.

THE PATENTS

- 14. Iridex is the owner and assignee of United States Patent No. 6,800,076 ("the '076 patent") entitled, "Soft Tip Cannula and Methods For Use Thereof." A true and correct copy of the '076 patent is attached hereto as Exhibit A. The '076 patent was duly and legally issued by the United States Patent and Trademark Office on October 5, 2004, to Mark Humayun as the inventor and Retinalabs, Inc., as the assignee. RetinaLabs, Inc., has since assigned all rights, title and interest in and to the '076 patent to Iridex. Iridex continues to hold all rights, title and interest in and to the '076 patent.
- 15. Iridex is the owner and assignee of United States Patent No. 7,537,593 ("the '593 patent"), entitled "Soft Tip Cannula and Methods for Use Thereof." A true and correct copy of the



'593 patent is attached hereto as Exhibit B. The '593 patent was duly and legally issued by the United States Patent and Trademark Office on May 26, 2009, to Mark Humayun as the inventor and Retinalabs.com, Inc., as the assignee (whose name later was clarified to be RetinaLabs, Inc.). RetinaLabs, Inc., has since assigned all rights, title and interest in and to the '593 patent to Iridex. Iridex continues to hold all rights, title and interest in and to the '593 patent.

THE ALCON PRODUCTS

On information and belief, the Alcon defendants make and sell in the United States 16. 20-gauge, 23-gauge and 25-gauge soft tip cannulas with green (and other colors) silicone ends (collectively, "Alcon colored soft tip cannulas") under one or more the product names Accurus® Surgical System 23-Gauge Soft-Tip Cannula, Grieshaber® DSP and/or Micro-Incision Vitrectomy Surgery ("MIVS") tips, product numbers including but not limited to 8065149525, 8065149523 and 8065149520. (See, e.g., http://www.alconretina.com/products/mivs/25gauge.asp and http://www.alconretina.com/products/grieshaber/grieshaberDSPTips.asp.) The Alcon colored soft tip cannulas are sold alone or in combination with a Grieshaber® backflush device, marketed for use as "active and passive aspirators," or as part of a package of instruments sold to work with the Constellation® Vision System. (http://www.alconretina.com/products/mivs/25gauge.asp.) A key feature by which Alcon markets the Alcon colored soft tip cannulas is the "green tip color improves tip visualization under air." (http://www.alconretina.com/products/mivs/25gauge.asp.) The Grieshaber® DSP Tips are marketed for use as vitreoretinal instruments. (http://www.alconretina.com/products/grieshaber/grieshaberDSPTips.asp.) These instruments are marketed for use in ophthalmic surgery, including vitrectomy surgery. On information and belief, the Constellation® Vision System is programmed to instruct the particular use of the Alcon colored soft tip cannulas. Alcon's colored soft tip cannulas are sold in competition with Iridex's GreenTip™ Soft Tip Cannulas.

ALCON'S WILLFUL INFRINGEMENT

17. Alcon has engaged and continues to engage in a pattern of conduct demonstrating: Alcon's awareness of the '076 and '593 patents; the objectively high likelihood that Alcon's actions constituted and continue to constitute infringement of claims of the '076 and '593 patents



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and that the patents are valid and enforceable; that this objectively-defined risk was so obvious that Alcon should have known it; and that Alcon in fact knew of this objectively-defined risk.

- November 2006, when Iridex's predecessor-in-interest, RetinaLabs, Inc., first made Alcon aware of the '076 patent and its relevance to the Alcon soft-tip products, and of the '593 patent since in or about May 2009, when the '593 patent issued, or at least by August 2010 when Iridex identified the '593 patent to Alcon. After obtaining the rights, title and interest to the '076 and '593 patents, Iridex continued to discuss with Alcon the coverage of the Alcon soft-tip products by the Iridex patents. Demonstrating Alcon's awareness of the objectively high likelihood that its actions constituted infringement of the '076 and '593 patents, Alcon offered no response that its products were not covered by Iridex's patents, yet chose to continue to sell the products at issue, in violation of the '076 and '593 patents. Alcon has not ceased selling the infringing products since learning of the '076 and '593 patents, in willful disregard for Iridex's patent rights.
- 19. On information and belief, Paul Hallen, a current Alcon employee, disputes Iridex's ownership of the '076 and '593 patents based on rights to the Iridex patents he allegedly obtained when he was a former RetinaLabs employee. While employed by RetinaLabs as the Vice President of Research and Development, Mr. Hallen owed a duty to assign to RetinaLabs any inventions he discovered during his employ. Mr. Hallen understood this duty, as demonstrated by his assignment to RetinaLabs of his rights to those patents that did result from Mr. Hallen's work while employed by RetinaLabs. On information and belief, Mr. Hallen, having left RetinaLabs for Alcon, now claims to be a co-inventor of the Iridex '076 and '593 patents. Contrary to his duty to assign any inventions he made while employed by RetinaLabs to RetinaLabs, on further information and belief, Mr. Hallen claims his "rights" in the Iridex patents were not assigned to Iridex. Mr. Hallen is not a named inventor of the '076 or '593 patents, Iridex is aware of no corroboration that Mr. Hallen is an inventor of any claim of the '076 and '593 patents and there is no public record of any assignment by Mr. Hallen to another.
- 20. In light of Mr. Hallen's duty to assign inventions to RetinaLabs, even if there were any corroboration showing Mr. Hallen to be an inventor, any rights to the inventions of the '076



and '593 patents Mr. Hallen might have had as an inventor were owed to RetinaLabs, who employed Mr. Hallen at the time. Moreover, Iridex's ability to fully investigate Mr. Hallen's assertions of inventorship has been severely hindered as, on information and belief, upon leaving RetinaLabs' employ, Mr. Hallen reformatted the hard drive of the RetinaLabs laptop computer assigned to Mr. Hallen for use during his employ, thereby erasing RetinaLabs documents, and failed to return physical files of RetinaLabs (now Iridex) pertaining to Iridex's patents at issue in this lawsuit. Any dispute of Iridex's ownership of the '076 and '593 patents under these facts, without any contemporaneous corroboration, is unreasonable and evidences willful infringement.

FIRST CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 6,800,076)

- 21. Iridex incorporates by reference paragraphs 1 through 20 above.
- 22. On information and belief, Alcon directly, indirectly, contributorily and/or by inducement, literally and/or under the doctrine of equivalents, has infringed and continues to infringe the '076 patent by its manufacture, use, sale, offer for sale and/or importation of products within this judicial district and elsewhere in the United States that infringe one or more claims of the '076 patent. Examples of infringing products include 20-gauge, 23-gauge and 25-gauge soft tip cannulas with colored silicone ends sold under one or more the product names Accurus[®] Surgical System 23-Gauge Soft-Tip Cannula, Grieshaber® DSP and/or Micro-Incision Vitrectomy Surgery ("MIVS") tips, product numbers including but not limited to 8065149525, 8065149523 and 8065149520, sold alone or as part of a Grieshaber® backflush device or as part of a package of instruments sold to work with the Constellation® Vision System. The Alcon colored soft tip cannulas are especially made or adapted for use in the methods claimed in the '076 patent and are not staple articles suitable for substantial noninfringing use. Aware of this and with knowledge of the '076 patent, Alcon instructs and encourages the use of Alcon colored soft tip cannulas in ophthalmic surgical procedures, including vitrectomy surgery, as "active and passive aspirators" and highlights the "green tip color" as improving visualization. On information and belief, Alcon sells the Alcon colored soft tip cannulas individually or as part of a system to doctors who purchase these Alcon products and use them in ophthalmic surgeries, including vitrectomy



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surgeries, upon Alcon's instruction and encouragement. On information and belief, when Alcon so instructs and encourages, it intends that the doctors will use the Alcon colored soft tip cannulas, the Grieshaber[®] backflush device and the Constellation[®] Vision System in ways that infringe the '076 patent and the doctors in fact do use the Alcon products in ways that infringe the '076 patent. Alcon's actions infringe one or more of the '076 patent claims, including but not limited to claims 1 and 17.

- 23. On information and belief, Alcon was aware of the '076 patent prior to the filing of this Complaint but recklessly continued to make, use, sell, offer for sale and/or import products, and instruct and encourage doctors to use these products in ophthalmic surgeries, knowing that such actions constitute a high likelihood of infringement of the '076 patent. Alcon acted and continues to act despite an objectively high likelihood that its actions constituted and continue to constitute infringement of a valid and enforceable patent; this objectively-defined risk was so obvious that it should have been known to Alcon; and in fact Alcon acted and continued to act knowing of this objectively-defined risk. Alcon's infringement of the '076 patent is thus willful.
- 24. Alcon's infringement of the '076 patent has caused and, unless enjoined, will continue to cause, irreparable harm to Iridex. Iridex has no adequate remedy at law and is entitled to a permanent injunction against further infringement.
- 25. Iridex has suffered and will continue to suffer damage to its business by reason of Alcon's acts of infringement of the '076 patent as alleged herein and Iridex is entitled to recover from Alcon the damages sustained as a result of Alcon's acts pursuant to 35 U.S.C. § 284.
- 26. Iridex is informed and believes, and on that basis alleges, that Alcon's actions make this an exceptional case within the meaning of 35 U.S.C. § 285, which entitles Iridex to an award of attorneys' fees.

SECOND CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 7,537,593)

- 27. Iridex incorporates by reference paragraphs 1 through 20 above.
- 28. On information and belief, Alcon directly, indirectly, contributorily and/or by inducement, literally and/or under the doctrine of equivalents, has infringed and continues to

